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EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,984	SCHAUB, ADREAS F.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-37,39 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-37,39 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 January 2011 has been entered.

Status of claims

2. Claims 28-37, 39, and 41-44 are pending in this application.

3. Addition of new claim 44 is acknowledged.

4. Claims 28-37, 39, and 41-44 are examined.

Claim Rejections - 35 USC § 112 – Withdrawn Rejections

5. The rejection of claim 43 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's arguments and evidence presented showing that one of the carbopols specified in the specification (i.e., Carbopol 934P) is a crosslinked polyacrylic acid.

6. The rejection of claims 28-37, 39, and 41-43 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's arguments that one skilled in the art would

know the metes and bounds of "isotonicizing substances", as evidenced by, for example, Muller (US Patent 5,624,903, cited in the previous Office action mailed 18 August 2010).

7. The rejection of claims 35 and 36 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments to claims 35 and 36.

8. The rejection of claim 37 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment to claim 37.

Claim Rejections - 35 USC § 112 – First Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. **Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 44 is drawn to applying an effective amount of an organic lubricant composition which comprises a lubricant film-forming combination consisting of at least one polyacrylic acid, at least one humectant, and water. However, the specification does not specifically teach a lubricant film-forming combination consisting of (i.e., a combination which may only have the ingredients) at least one polyacrylic acid, at least

one humectant, and water. Applicant asserts that support for new claim 44 is found on page 4, lines 4-24, the paragraph bridging pages 5 and 6, and pages 5-7 (page 23 of Applicant's Remarks filed 18 January 2011). However, none of these passages recites the specific combination of only at least one polyacrylic acid, at least one humectant, and water as a lubricant film-forming combination. Therefore, the limitation of a lubricant film-forming combination consisting of at least one polyacrylic acid, at least one humectant, and water constitutes new matter.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 28, 30, 32, 34, 37, 39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara et al (US Patent 3,971,848, "Kasahara '848", previously cited) in view of Van Leuven (US Patent 4,267,168, previously cited) as evidenced by Muller et al (US Patent 5,624,903) and Bringloe (US Patent 4,765,478, previously cited).

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, which comprises applying effective amounts of an organic lubricant comprising a polyacrylic acid; isotonicizing substances; a humectant; and no alkali metal salts of

metaphosphates; wherein said composition is in the form of a paste, gel, cream, suppository, or foam; according to the steps recited in claim 28 (see claim 28).

Kasahara '848 teaches a composition having lubricating property comprising fucoidin and alginic acid (abstract) and does not contain alkali metal metaphosphates. The composition may be used to lubricate the birth canal in human bodies to facilitate the delivery of the fetus (col. 5, lines 16-32). The composition may be optionally mixed with sodium polyacrylate and carboxymethyl cellulose (col. 5, lines 39-42). Kasahara '848 further teaches that the addition of sodium polyacrylate is preferable to afford lubrication at the time of parturition, and the addition of a viscous substance (i.e., a thickener) such as carboxymethyl cellulose results in a composition having a further improved lubrication (col. 2, lines 21-36), and therefore one skilled in the art would be motivated to include said substances in the composition. Kasahara '848 further teaches that, in order to heighten the solubility of the compositions, it is preferred at the time of application to blend the compositions with glucose (col. 5, lines 43-45). Glucose is an isotonicizing substance, as evidenced by Muller et al, which teaches that glucose is an isotonicizing agent (see col. 4, lines 9-10).

While Kasahara '848 teaches the presence of a polyacrylic acid and glucose (isotonicizing substance), Kasahara '848 is silent with respect to the presence of a humectant in the composition.

Van Leuven teaches that the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the humectants propylene glycol and/or glycerine to the composition of Kasahara '848; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of said humectant(s) provides the benefits of a very soothing action on tender tissue, as with glycerin, and some bacteriocidal activity, as with propylene glycol, as taught by Van Leuven (see col. 6, lines 1-2 and col. 5, lines 47-49, respectively). One would reasonably expect success from the addition of propylene glycol and/or glycerin as taught by Van Leuven to the composition of Kasahara '848 because both references are drawn to compositions useful for lubricating the birth canal during delivery.

Regarding the form of the composition, Kasahara '848 teaches that the composition is a "mucous, thready composition having lubricating property" (col. 2, lines 7-8) and that carboxymethyl cellulose is a viscous substance (col. 2, lines 31-35), and therefore one skilled in the art would reasonably expect the composition to be in the form of a gel; as further evidence, Bringloe teaches that carboxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53), which would also favor the formation of a gel composition.

Regarding the application steps of the composition (claims 28, 37, 39, and 41), Kasahara '848 exemplify application of the composition just before parturition (col. 5, lines 27-30). The phrase "just before parturition" reasonably reads on before labor or dilation begins, as well as during the dilation phase. While Kasahara '848 is silent with respect to multiple application steps as now recited in amended claim 28, it would have

been obvious to a person having ordinary skill in the art at the time the invention was made to apply the same composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan. Regarding forming a lubricant layer, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect a lubricant layer to be formed between the birth canal surface and the item to be delivered.

Regarding claim 30, Kasahara '848 teaches that the viscous substance (thickener) carboxymethyl cellulose may be added to the composition.

Regarding claim 32, Van Leuven teaches the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

Regarding claim 34, Kasahara '848 teaches that the composition to be used for lubricating the birth canal of humans comprises water (see col. 5, lines 21-32).

Regarding claim 42, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect the composition to have a greater adhesion to the surface of the birth canal compared with the skin of the fetus.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of JP 46-24256 ("JP '256", previously cited).

Claim 29 of the claimed invention is drawn to the method of claim 28, wherein said polyacrylic acid is present in a concentration of from 0.25 to 5% by weight.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of sodium polyacrylate in the composition.

JP '256 teaches that sodium polyacrylate is useful as a lubricant during birth, and that the lubricant does not lose its activity when diluted to 0.2-0.3% concentration. This amount overlaps that of the claimed invention. One skilled in the art would be motivated to manipulate the amount of sodium polyacrylate from within said ranges by routine experimentation, in order to optimize the lubricity of the resultant composition.

14. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of Behl et al (US Patent 5,580,574).

Claim 31 of the claimed invention is drawn to the method of claim 30, wherein said cellulose is present in a concentration of from 1 to 3% by weight.

The invention of the combined references is delineated above (see paragraph 12). As noted above, Kasahara '848 teaches that carboxymethyl cellulose may be added to the composition (col. 5, lines 39-40).

The invention of the combined references is silent with respect to the amount of cellulose in the composition.

Behl et al teach pharmaceutical compositions for transdermal delivery (abstract). The compositions include gelling agents in amounts sufficient to obtain a desired consistency of the gel; amounts of carboxymethyl cellulose are preferably in the range of from about 2 to 5 percent by weight of the composition (col. 2, line 59 - col. 3, line 5). This amount overlaps that of the claimed invention. One skilled in the art of topical compositions would be motivated to manipulate the amount of carboxymethylcellulose taught in Kasahara '848 from within said ranges by routine experimentation, in order to optimize the desired consistency of gel as taught by Behl et al.

15. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of Kasahara et al (US Patent 3,814,797, "Kasahara '797", cited by Applicants in the IDS filed 7/21/04).

Claims 35 and 36 of the claimed invention are drawn to the method of claim 28, wherein between 5 to 200 mL (claim 35) or between 10 to 100 mL (claim 36) of said composition is introduced into birth canal.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of composition introduced into the birth canal.

Kasahara ‘797 teaches aqueous lubricating compositions for imparting lubricity to the parts of living bodies (abstract). The aqueous compositions may be applied to human beings (col. 3, lines 50-51). For use in human delivery, Kasahara '797 exemplify an amount of 100 mL of the composition (see Example 2, column 4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use an amount of the composition of the combined references of 100 mL; thus arriving at the claimed invention. When determining an appropriate amount, one skilled in the art would look for guidance from the teachings in the prior art of other lubricant compositions used in human delivery, such as Kasahara ‘797. Therefore, one skilled in the art would be motivated to select an amount of lubricating composition according to the teachings of Kasahara ‘797, absent evidence to the contrary.

16. **Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara ‘848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further evidenced by Dettmar (US Patent 4,652,446)**.

Claim 43 of the claimed invention is drawn to the method of claim 28, wherein the polyacrylic acid is a crosslinked polyacrylic acid.

The invention of the combined references is delineated above (see paragraph 11). As noted above, Kasahara '848 teaches that the composition may be mixed with sodium polyacrylate (col. 5, lines 39-42). The term “sodium polyacrylate” denotes the sodium salt of a polyacrylic acid which may be linear or cross-linked; as evidence, Dettmar teaches that the phrase “sodium polyacrylate” denotes the sodium salt of a polyacrylic acid which may be linear or cross-linked in mucosal-protecting compositions (col. 1, lines 44-46).

The following rejections are newly applied:

17. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara ‘848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32, 34, 37, 39, 41, and 42 above, and further in view of Roder et al (US Patent 6,217,885).

Claim 33 of the claimed invention is drawn to the method of claim 28, wherein said composition comprises carob flours in a concentration of from 0.5 to 3% (see claim 33).

The invention of the combined references is delineated above (see paragraph 11). Kasahara ‘848 teaches that, when viscous substances such as alkali salt of alginic acid, gum Arabic and carboxymethyl cellulose are added, the resulting composition has a further improved lubrication (col. 2, lines 29-36).

The invention of the combined references does not specifically teach that one of the viscous substances may be carob flour.

Roder et al teach cosmetic and/or pharmaceutical compositions for use on human or animal skin (abstract), which may be in the form of gels, creams or foams (col. 3, lines 46-47), and wherein preferably 0.1 to 2% of thickeners and gelling agents can be employed, which include cellulose derivatives, alginates, and carob bean flour (col. 6, lines 38-42). The amount of gelling agent employed overlaps that of the claimed invention; one skilled in the art would be motivated to manipulate the amount of gelling agent from within said ranges by routine experimentation, in order to optimize the consistency of the resultant composition.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select carob flour as one of the thickeners in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because alginates and cellulose derivatives, and carob flour, are all known thickeners and gelling agents in topical compositions for human or animal skin as taught by Roder, and therefore are functionally equivalent to one another. Therefore, it would be well within the purview of the skilled artisan to choose either compound as one of the thickeners of the composition of the combined references, since the prior art establishes the functional equivalency of carob flour and cellulose derivatives and alginates.

18. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168, previously cited) in view of JP 46-24256 ("JP '256", previously cited).

Claim 44 of the claimed invention (newly added) is drawn to a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, which comprises applying effective amounts of an organic lubricant composition comprising a lubricant film-forming combination consisting of at least one polyacrylic acid, at least one humectant, and water, and no alkali metal salts of metaphosphates; wherein said composition is in the form of a paste, gel, cream, suppository, or foam; according to the steps recited in claim 44 (see claim 44).

Van Leuven teaches compositions which act as lubricants to be used during delivery at the time of birth (abstract). The glycerine provides a soothing action on tender tissue, and is used in amounts which provide an adequate range of lubricity in the composition (col. 6, lines 1-7); therefore, the composition may comprise a lubricant consisting of glycerine. The composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54).

While Van Leuven teaches a composition comprising a lubricant consisting of glycerine to aid in the delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother, Van Leuven does not specifically teach the use of a combination consisting of glycerine, polyacrylic acid, and water as the lubricant.

JP '256 teaches a lubricant consisting essentially of a polyacrylate (preferably sodium or ammonium) shows good lubricating properties, and is applied to the animals vagina by painting at the time of birth. The lubricant may be supplied as a water-soluble dust, and does not lose its activity when diluted to 0.2-0.3% concentration (see abstract), and therefore may be diluted with water.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add sodium polyacrylate and water lubricant to the glycerine lubricant of the composition of Van Leuven; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because the ingredients of sodium polyacrylate diluted in water is known to have good lubricating properties, and both compositions are useful for providing lubrication at the time of birth.

Regarding the application steps of the composition, Van Leuven teaches that the composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue (i.e., the birth canal) of the baby's mother (col. 6, lines 53-54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the same composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan.

Regarding forming a lubricant layer, Van Leuven teaches that the composition is useful as a lubricant to be used during delivery at the time of birth (e.g., see abstract), and therefore one skilled in the art would reasonably expect the composition to form a lubricant layer between the birth canal surface and the item to be delivered.

Response to Arguments

19. Applicant's arguments filed 18 January 2011 have been fully considered but they are not persuasive.

Applicant first argues that the prior art does not suggest the presently claimed method steps, arguing that the cited references do not teach a second method step of additionally applying an amount of the composition to the birth canal surface during labor, and do not teach an active method step of applying additional amounts of the composition to maintain the lubricant layer until the item to be delivered is delivered (pages 9-11 of Applicant's Remarks filed 18 January 2011).

This argument is not persuasive. Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). In this case, that Kasahara does not teach a second step of applying additional lubricant does not render the claims unobvious; since the purpose of the composition of the combined references is keeping the birth canal lubricated during delivery, one skilled in the art would recognize that additional amounts of lubricating composition can, and would, be applied as needed in order to maintain this lubricity, absent evidence to the contrary.

Applicant also argues that the prior art does not suggest the composition for use in the presently claimed method, submitting that the Examiner's reliance on the mention of CMC in Kasahara in rejecting the distinguishing feature is based on improper hindsight. Applicant argues that the composition for use in the claimed method has unexpected properties that cannot be realized if prepared in the form of an aqueous solution as in Kasahara (pages 11-12 of Remarks).

This argument is not persuasive. Applicant appears to be arguing that, if the composition of Kasahara is an "aqueous solution", then it cannot have the properties of a gel; however, this is not the case, since 1) Kasahara clearly teaches that the addition of a viscous substance (i.e., a thickener) such as carboxymethyl cellulose (i.e., CMC) results in a composition having a further improved lubrication (col. 2, lines 21-36), and therefore one skilled in the art would be motivated to include said substances in the composition; 2) CMC is a known gelling agent in topical compositions, as evidenced by Bringloe (see col. 3, lines 46-53); and 3) Kasahara clearly teaches that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect that the composition of Kasahara may be in the form of a gel. That Kasahara teaches its composition as an "aqueous solution" does not mean it cannot be a gel; it is noted that Applicant's composition also falls within the definition of an "aqueous solution", since it may further comprise water (see claim 34).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant also argues that the Kasahara composition is unsuitable for the use alleged by the Examiner, asserting that, if the formulation of Kasahara is used, the practitioner would be impaired in his ability to supervise the birthing process, and the composition of Kasahara would no longer have the desired properties if one were to attempt to sterilize it (pages 12-13 of Remarks).

This argument is not persuasive because the features upon which applicant relies (i.e., supervising the birthing process and sterilizing the composition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to reducing the frictional force between an item to be delivered and a birth canal surface of a mother in human vaginal child birthing; since Kasahara teaches that the substances have a lubricating property and are not likely to escape between the frictional interfaces of the animals (col. 2, lines 12-30), and that the composition can be effectively applicable to the animals as well as the human bodies for the delivery of a

fetus (col. 5, lines 16-32), the teachings of the combined references meet the limitations of the claims for this reason and for other reasons as stated herein.

Applicant also argues that there remains an unsatisfied and long-felt need for the present claimed method, asserting that the Examiner does not appear to dispute that there was a long-felt need for a method as presently claimed, and citing previously submitted declarations which avow that the method of Kasahara is not currently practiced and that attempts to reproduce Kasahara's method have been unsuccessful. Applicant asserts that, if Kasahara had solved the need, there should be some record of the method in medical protocols or literature. Applicant argues that the practice papers by Lamaze International entitled “Care Practices that Promote Normal Birth” provide further evidentiary support for Applicant’s position that there was a long-felt and unmet need. Applicant also argues that the results of the enclosed market research survey show that women and physicians consider there to be a need for such a product [as the claimed invention], thereby demonstrating unsatisfied need (pages 13-15 of Remarks).

This argument is not persuasive. Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors: First, the need must have been a persistent one that was recognized by those of ordinary skill in the art; second, the long-felt need must not have been satisfied by another before the invention by applicant; and third, the invention must in fact satisfy the long-felt need. See MPEP 716.04. Applicant’s evidentiary documents and previously submitted declarations attempting to establish

long felt and unmet need have been fully considered, but are not persuasive for overcoming the rejection. It is first noted that the Examiner does not acquiesce to Applicant's assertion that there was a long-felt need for a method as presently claimed; rather, the previous Office action merely states that Applicants have not provided objective evidence correlating how the claimed invention satisfies any long-felt and unmet needs cited by Applicant; see page 16 of Office action mailed 18 August 2010. In response to Applicant's arguments regarding Kasahara, it is noted that, while the Declaration of 5/17/10 and arguments state, "the composition of Kasahara did not have the necessary properties required for human birthing in terms of lubrication, appearance, reproducibility, standard guideline for production, sterility, commercial applicability, or shelf-life", Applicants have not presented any data to demonstrate said conclusions. While it is noted that the Declaration of 6/4/10 attempts to show the gel adapted from Kasahara, the pictures submitted are dark and the color of the gel cannot be determined. Assuming that the gel is as described (i.e., viscous and dark-brown), the gel, while not a "commercially applicable" color, would still be capable of use as a lubricant. Kasahara teaches that the viscous substances in its composition form synergistically a liquid film of much greater thickness, which is not likely to escape between the two frictional interfaces (col. 2, 36-40), and Applicant has not presented any objective evidence to the contrary, but simply has made conclusory statements opposing the teachings of Kasahara. Said statements, while in the form of a declaration, are still not persuasive for overcoming the rejection. In response to Applicant's arguments regarding the Lamaze papers and the survey by GFK, it is noted

that said papers are directed to promoting, protecting, and supporting normal birth, as well as opinions regarding the product Dianatal, but neither are specifically directed to reducing the frictional force between an item to be delivered and a birth canal surface of a mother. Instead, the references are directed to other issues such as birthing position, movement, and bonding between mother and baby, as well as general interest in the product Dianatal. Additionally, neither of the references show that others were working on the problem of reducing the frictional force between an item to be delivered and a birth canal surface of a mother, but failed. Furthermore, while the survey by GFK shows a level of interest in the Dianatal, it does not demonstrate that it satisfies any problem with reducing the frictional force between an item to be delivered and a birth canal surface of a mother. Therefore, the references are not sufficient to establish long-felt and unmet need for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing.

Applicant also argues that the presently claimed method has "unexpected and surprising advantages" in view of recommended modern birthing techniques, asserting that the presently claimed method uses a composition with "surprising bioadhesive properties", which provide the unexpected advantage of allowing the laboring woman to be ambulatory with the lubricant in place during labor, and allows a mother to give birth in any position, including non-supine positions. Applicant argues that aqueous solutions, such as those used in the veterinary arts and in Kasahara, would not be applicable in humans because they would be expelled by the mother's movement and/or during water birth, and also by the progression of the item to be delivered

through the birth canal, and a practitioner cannot safely or practically continuously pump an aqueous lubricant into a human mother as is the procedure in animals (pages 15-17 of Remarks).

This argument is not persuasive. Applicants do not point to what exactly are the “surprising bioadhesive properties”, or where they are found in the specification or declarations. Applicant’s assertions regarding the properties of the composition of Kasahara have not been supported by objective evidence. Kasahara teaches that its compositions form a film of much greater thickness which is not likely to escape between the frictional interfaces (col. 2, lines 36-40), and that it has been confirmed that the composition can be effectively applicable to the animals as well as the human bodies (col. 5, lines 20-32). Therefore, one skilled in the art would not expect the composition to be expelled, and that the "aqueous lubricant" of Kasahara, as categorized by Applicants, would in fact be applicable to humans, and Applicants have not provided objective evidence otherwise. As previously noted, the composition of the claimed invention is also an “aqueous lubricant”, since it may further comprise water (e.g., see claim 34).

Applicant finally argues that the presently claimed method and composition are supported by clinical trial data and regulatory approval, and asserts that it is clear that there is a need, i.e., reduction in perineal tears and labor time, satisfied by the presently claimed method. Applicant argues that the previous submitted declaration shows that the composition of Kasahara did not have the necessary properties required for human birthing, and thus was not able to use the composition based on the disclosure in

Kasahara. Applicant argues that the presently claimed method has undergone clinical trials and is approved by medical regulatory agencies in many countries, but the methods cited from the prior art are not approved and there is no evidence of any clinical trials (pages 17-19 of Remarks).

This argument is not persuasive. As noted above, while the Declaration of 5/17/10 and arguments state, "the composition of Kasahara did not have the necessary properties required for human birthing in terms of lubrication, appearance, reproducibility, standard guideline for production, sterility, commercial applicability, or shelf-life", Applicants have not presented any data to demonstrate said conclusions. Kasahara teaches that its composition can be used very conveniently as an agent for lubricating the birth canal at the time of parturition, and is effectively applicable to human bodies (col. 5, lines 16-32), and Applicants have not presented evidence to the contrary, and therefore fail to establish that the need of reducing frictional force between an item to be delivered and a birth canal surface of a mother in human vaginal child birthing is long felt and unmet.

In response to Applicant's arguments regarding claim 29 (pages 20-21 of Remarks), it is noted that the rejection is not based on JP '256 alone, but rather Kasahara et al in view of Van Leuven as evidenced by Muller et al and Bringloe, and further in view of JP '256. One skilled in the art, looking to optimize the amount of sodium polyacrylate in the composition of the combined references, would look to the teachings of JP'256 and consider them relevant, since both teach use of sodium

polyacrylate in lubricating compositions. JP '256 need not specify human childbirth, since this teaching is already taught in Kasahara '848.

In response to Applicant's arguments regarding claim 31 (pages 21-22 of Remarks), it is noted that the rejection is not based on Behl alone, but rather Kasahara et al in view of Van Leuven as evidenced by Muller et al and Bringloe, and further in view of Behl. One skilled in the art, looking to optimize the amount of carboxymethyl cellulose in the composition of the combined references, would look to the teachings of Behl and consider them relevant, since both teach use of CMC in lubricating compositions. Furthermore, Behl teaches that the purpose of CMC in its compositions is to obtain the desired consistency of the gel (col. 2, lines 59 – col. 3, line 5), not to facilitate or enhance transdermal penetration.

In response to Applicant's arguments regarding claims 35 and 36 (page 22 of Remarks), it is noted that said claims depend from claim 28 have not been argued separately from claim 28; since the method of claim 28 is rendered obvious for reasons stated above, claims 35 and 36, which depend from claim 28, are also rendered obvious for reasons stated above.

In response to Applicant's arguments regarding claim 43 (page 22 of Remarks), it is noted that claim 43 depends from claim 28 and has not been argued separately from claim 28; since the method of claim 28 is rendered obvious for reasons stated above, claim 43, which depends from claim 28, is also rendered obvious for reasons stated above.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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BSF

/Ashwin Mehta/

Primary Examiner, Art Unit 1638